



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/749,120	12/30/2003	Richard Boyd	NOR-015CP2 and 286336.154	3284
23483 7590 WILMERHALE/BOSTON 60 STATE STREET BOSTON, MA 02109	04/08/2009		EXAMINER SAUNDERS, DAVID A	
			ART UNIT	PAPER NUMBER
			1644	
			NOTIFICATION DATE	DELIVERY MODE
			04/08/2009	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

michael.mathewson@wilmerhale.com
teresa.carvalho@wilmerhale.com
sharon.mathews@wilmerhale.com

Office Action Summary

Application No.

10/749,120

Applicant(s)

BOYD ET AL.

Examiner

David A. Saunders

Art Unit

1644

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on 12 December 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 38-44, 46-57, 61-64, 66-84, 89, 90, 92 and 94-100 is/are pending in the application.
- 4a) Of the above claim(s) 43, 61-64, 66-84, 90, 92 and 94-98 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 38-42, 44, 48-56, 89 and 99 is/are allowed.
- 6) ☒ Claim(s) 46, 47, 57 and 100 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☒ Notice of Draftsperson's Patent Drawing Review (PTO-846)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date 12/12/08
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

AMENDMENT ENTRY

Amendment of 12/12/08 has been entered.

Claims 38-44,46-57,61-64,66-84,89-90,92,94-100 are pending. Claims 38-42,44,46-57,89 and 99-100 are under examination. Multiple dependent claim 100 is under examination only to the extent that it depends from elected claim 46.

CORRECTIONS REGARDING PREVIOUS OFFICE ACTION

The following corrections pertain to the previous Office action:

At page(s) 2, in the statement of the 112, First Para. rejection, "58" should have read as --89--. Claim 58 had already been cancelled. Claim 89 is the independent claim, along with claim 38, that was rejected for reciting new matter.

OBJECTION(S)/REJECTION(S) OF RECORD WITHDRAWN

The amendment has overcome previously stated issues as follows:

The rejection under 35 USC 112, 2nd paragraph of claims 46-49, due to the change in dependency of claim 46.

The rejection under 35 USC 112, 1st paragraph of claims 38-42,44,46-57,89 and 99-100. Applicant's urgings concerning the teachings at specification p 12 are convincing that there is original disclosure support for combining TREC analysis with any of the other diagnostic methods taught in the Summary of the Invention beginning at page 10, line 27.

MAINTAINED REJECTION(S) UNDER 35 USC 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 46-47, 57 And 100 are rejected under 35 U.S.C. 102(b) as being anticipated by Boyd et al (US 2002/0136704, cited on Form PTO-892) .

This reference is cited under 102 (b) since it has a publication date more than 1 year prior to the instant filing date of 12/30/03. This reference corresponds to earlier filed application 09/977,074, for which applicant claims benefit of its earlier filing date.

The disclosure therein pertaining to the measurement of a blood or serum marker and to TREC analysis supports instant claim 38 as much as does the instant disclosure (which is no support under 112); thus for the purposes of prior art considerations, instant claim 38 is not rejected. The disclosure therein pertaining to the pharmaceuticals administered, however, cannot support instant dependent claims 46-47and 100. For example, at the least, "SERMs, SARMs, SPRMs" are not supported in instant claim 46. For example, at the least, "DECAPEPTYLY" and "Gonadorelin" are not supported in instant claim 47. The recitation of "ketoconazole" is not supported in instant claim 100.

The disclosure of US 2002/0136704 pertaining to the markers measured cannot support instant dependent claim 57. For example, at the least, "CXCL12, CXCL19" are not supported in instant claim 57.

The number of pharmaceuticals/markers recited in each of claims 46-47 and 57 is excessively long for the examiner to search each Markush group member. In order to overcome the rejection, Applicant must cancel all Markush members in the instant claims which lack support in the earlier documents. See MPEP201.11.

Claims 46-47, 57 And 100 are rejected under 35 U.S.C. 102(a) or (e) as being anticipated by Boyd et al (US 2003/0017153, cited on Form PTO-892) .

This reference is cited under 102 (a) since it has a publication date less than 1 year prior to the instant filing date of 12/30/03. This reference is cited under both 102 (a) and (e) since it has a different inventive entity from that instantly. This reference corresponds to earlier filed application 09/885,268, for which applicant claims benefit of its earlier filing date.

The disclosure therein pertaining to the pharmaceuticals administered cannot support instant dependent claims 46-47 and 100. The disclosure therein of the markers measured cannot support instant dependent claim 57. The rational follows that set forth supra with respect to reference US 2002/0136704.

Applicant's response of 12/12/08 has misinterpreted the examiner's position by characterizing it as contradictory, in that the rejection has stated that Boyd (2002) and Boyd (2003) fail to show all aspects of instant claims 46-57, 57 and 100 and yet has rejected these under 102. Applicant should note that, while "each and every element" of the claim must be anticipated for a 102 rejection, not "each and every" member of a Markush group must be shown by the anticipating reference, since the members of the Markush group are recited in the alternative.

Applicant' has urged that the examiner did not provide any rational for the rejection. The examiner did not need to explain the rational in detail, because the examiner pointed applicant to MPEP 201.11 (see p 6, 2nd full para.). This section of the MPEP clearly explains the rational for stating a 102 rejection of a claim, in a CIP application, which cannot be fully supported by the disclosure of an earlier filed parent application.

201.11 MANUAL OF PATENT EXAMINING PROCEDURE Rev. 5, Aug. 2006 200-60

Any claim in a continuation-in-part application which is directed *solely* to subject matter adequately disclosed under 35 U.S.C. 112 in the parent nonprovisional application is entitled to the benefit of the filing date of the parent nonprovisional application. However, if a claim in a continuation-in-part application recites a feature which was not disclosed or adequately supported by a proper disclosure under 35 U.S.C. 112 in the parent nonprovisional application, but which was first introduced or adequately supported in the continuation-in-part application, such a claim is entitled only to the filing date of the

continuation-in-part application; *In re Chu*, 66 F.3d 292, 36 USPQ2d 1089 (Fed. Cir. 1995); *Transco Products, Inc. v. Performance Contracting Inc.*, 38 F.3d 551, 32 USPQ2d 1077 (Fed. Cir. 1994); *In re Van Lagenhoven*, 458 F.2d 132, 136, 173 USPQ 426, 429 (CCPA 1972); and *Chromalloy American Corp. v. Alloy Surfaces Co., Inc.*, 339 F. Supp. 859, 874, 173 USPQ 295, 306 (D. Del. 1972).

By way of further illustration, if the claims of a continuation-in-part application which are only entitled to the continuation-in-part filing date "read on" published, publicly used or sold, or patented subject matter (e.g., as in a genus-species relationship) a rejection under 35 U.S.C. 102 would be proper. Cases of interest in this regard are as follows: *Mendenhall v. Cedarapids Inc.*, 5 F.3d 1557, 28 USPQ2d 1081 (Fed. Cir. 1993); *In re Lukach*, 442 F.2d 967, 169 USPQ 795 (CCPA 1971); *In re Hafner*, 410 F.2d 1403, 161 USPQ 783 (CCPA 1969); *In re Ruscetta*, 255 F.2d 687, 118 USPQ 101 (CCPA 1958); *In re Steenbock*, 83 F.2d 912, 30 USPQ 45 (CCPA 1936); and *Ex parte Hageman*, 179 USPQ 747 (Bd. App. 1971).

If this rational is applied to a Markush group, recited in a claim of a CIP application, that recites more members than can be supported by the parent document, it follows that the claim in the CIP application is only entitled to the CIP filing date. Thus the earlier published Boyd references anticipate, by virtue of disclosing the subset of Markush group members of the CIP claim that are in common to the parent and to the CIP.

Applicant has also argued that the 2 Boyd references must "teach every element of the rejected claims". In order to reject a claim that recites a Markush group under 102, the examiner need only point out one, or a subset of, the Markush group members, because the Markush group members are recited in the alternative. Thus "each and every element" of the rejected claims can be shown by a reference that teaches only one, or a subset of, the Markush group members. Clearly, the Boyd references teach that subset of Markush group members which are also disclosed in the instant CIP application.

Applicant has also urged that the 102 rejections were unclear, by virtue of the examiner's statement that

"[t]he number of pharmaceuticals/markers recited in each of claims 46-47 and 57 is excessively long for the examiner to search each Markush group member. In order to overcome the rejection, Applicants must cancel all Markush group members in the instant claims which lack support in the earlier documents."

A CIP claim reciting unsupported members in a Markush group can be properly rejected, if the examiner points out only one recited unsupported member in the CIP claim. In the rejection of record the examiner pointed out 3 unsupported members that

are still recited in instant claim 46; the examiner thus pointed out more than was required to make the rejection of that claim. Where the examiner indicated that the Markush groups of claims 46-47 and 57 were excessively large, there was no indication that the examiner was requiring an election of species, since an election of species would be irrelevant to overcoming a 102 rejection based on the Boyd references (If applicant wants to think in terms of an "election of species" then the only possible "election" that could be made, in order to overcome the 102 rejection, would be for applicant to "elect" the species which are commonly taught in the parent and in the CIP disclosures).

If applicant wants to enhance prosecution, he can do so by cancelling all of the Markush group members which cannot be supported by the parent document(s), for which applicant claims benefit. If not, then the examiner can "play the Markush game" with applicant by pointing out the unsupported Markush group members of the excessively large Markush groups one at a time (in which case applicant will get a consideration of one member in a non-final action and another in a FINAL action, after which applicant will be required to fill another RCE).

Applicant's arguments filed 12/12/08 have been fully considered but they are not persuasive for the above reasons.

ART OF INTEREST

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Sekaly et al (2003/0228586, cited on PTO-892) is of interest for showing assays for TRECs.

FINALITY

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

This application contains claims 61-64, 66-84, 90, 92, 94-98 (of Groups II-III and VI) drawn to an invention nonelected with traverse in the reply filed on 4/10/07. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

Furthermore, any complete reply to the FINAL rejection must include an amendment that deletes the dependency of claim 100 from nonelected claim 75.

Withdrawn claim(s) 43, drawn to a nonelected species, shall be rejoined.

CONTACTS

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David A. Saunders, whose telephone number is 571-272-0849. The examiner can normally be reached on Mon.-Thu. from 8:00 am to 5:30 pm and on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eileen O'Hara, can be reached on 571-272-0878. The fax phone number for the organization where this application is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you

Art Unit: 1644

have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Typed 3/31/09 DAS

/David A Saunders/

Primary Examiner, Art Unit 1644